EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S, Plaintiff, v. SANOFI-AVENTIS, AVENTIS PHARMACEUTICALS INC., and AVENTIS PHARMA DEUTSCHLAND GMBH, Defendants.	)	C.A. No. 05-645-SLR

DEFENDANTS' SECOND CONSOLIDATED AND AMENDED ANSWER AND COUNTERCLAIMS

Aventis Pharmaceuticals Inc., sanofi-aventis, and Aventis Pharma Deutschland GmbH (herein sometimes referred to collectively as "Aventis") hereby consolidate and amend their previous answers and counterclaims (D.I. 8, 16) as follows. As a general and preliminary matter, Aventis notes that the Complaint retains references to Aventis Pharma AG, an entity that was dismissed from this action by Novo's Notice of Dismissal, filed December 2, 2005 (D.I. 14). Accordingly, Aventis hereby answers only on behalf of Aventis Pharmaceuticals, Inc., sanofi-aventis and Aventis Pharma Deutschland GmbH.[1] Aventis generally denies as improper any and all allegations in the Complaint that refer to Aventis Pharma AG, and nothing herein shall constitute or be construed as any admission, acknowledgement or waiver by Aventis Pharma AG.

[1] While the Complaint names Aventis Pharma Deutschland GmbH, this entity is now known as sanofi-aventis Deutschland GmbH. Accordingly, this current title will be used in this Second Amended Answer.

THE PARTIES

1. Aventis is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint and therefore denies each and every allegation contained in paragraph 1 of the Complaint.

2. No response is necessary, as paragraph 2 of the Complaint does not concern Aventis.

3. Aventis denies the allegations set forth in paragraph 3 of the Complaint, except admits that sanofi-aventis S.A. is a corporation organized and existing under the laws of France, having a place of business at 174/180 Avenue de France, Paris, Cedex 75013 France.

4. Aventis denies the allegations set forth in paragraph 4 of the Complaint, except admits that Aventis Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Somerset Corporate Blvd., Bridgewater, New Jersey 08807, and admits that Aventis Pharmaceuticals, Inc. is related to sanofi-aventis S.A.

5. Aventis denies the allegations set forth in paragraph 5 of the Complaint, except admits that sanofi-aventis Deutschland GmbH has a place of business at Industriepark Hoechst, D – 65926 Frankfurt am Main, Germany, and admits that sanofi-aventis Deutschland GmbH is related to sanofi-aventis S.A.

6. As set forth above, Aventis Pharma AG is no longer a defendant in this litigation. Accordingly, Aventis denies the allegations set forth in paragraph 6 of the Complaint as irrelevant and improper.

7. Aventis denies the allegations set forth in paragraph 7 of the Complaint.

8. No response is necessary as paragraph 8 of the complaint does not concern Aventis.

JURISDICTION AND VENUE

9. Aventis admits that Novo styled its cause of action as one for patent infringement under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. §§ 271 and 281-285.

10. Aventis admits that 28 U.S.C. §§ 1331 and 1338(a) give this Court subject matter jurisdiction over actions arising under the patent laws of the United States, Title 35, United States Code, and Aventis does not contest this Court's subject-matter jurisdiction under the provisions of 28 U.S.C. §§ 1331 and 1338(a) for purposes of this action only.

11. Aventis admits that Aventis Pharmaceuticals, Inc. sells various products and does business throughout the United States and in this District. Aventis otherwise denies the allegations contained in paragraph 11 of the Complaint.

12. Aventis admits that Aventis Pharmaceuticals, Inc. distributes medical devices that are distributed and used throughout the United States, including in this District. Aventis otherwise denies the allegations contained in paragraph 12 of the Complaint.

13. Aventis admits that Aventis Pharmaceuticals, Inc. was served in accordance with 8 Del.C. § 321, and Aventis Pharmaceuticals, Inc., sanofi-aventis S.A., and sanofi-aventis Deutschland GmbH do not contest the personal jurisdiction of this Court in this proceeding. Aventis denies that defendants have committed acts of infringement in Delaware and therefore denies the remaining allegations in paragraph 13 of the Complaint.

14. Aventis admits that venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(c) and 1400(b), although Aventis does not admit that this forum is the most convenient

forum under 28 U.S.C. § 1404, and denies the remaining allegations set forth in paragraph 14 of the Complaint.

FACTS

15. Aventis admits that Exhibit A to the Complaint purports to be a copy of United States Patent No. 6,582,408 ("the '408 patent"), entitled MEDICAL DEVICE, and appears to have been issued by the United States Patent and Trademark Office ("USPTO") on June 24, 2003. Aventis, however, denies that the USPTO duly and legally issued the '408 patent, and denies all other allegations of paragraph 15 of the Complaint.

16. Aventis lacks sufficient knowledge to form a belief as to the allegations of paragraph 16 of the Complaint and therefore denies them.

COUNT I

17. Aventis denies that defendants are directly infringing any of the claims of the '408 patent or contributing to or actively inducing infringement of any of the claims of the '408 patent by others. Aventis otherwise denies the allegations set forth in paragraph 17 of the Complaint.

18. Aventis denies that defendants are infringing the '408 patent and otherwise denies all other allegations set forth in paragraph 18 of the Complaint.

19. Aventis denies that defendants are infringing the '408 patent and otherwise denies all other allegations set forth in paragraph 19 of the Complaint.

20. Aventis denies that defendants are infringing the '408 patent and otherwise denies all other allegations set forth in paragraph 20 of the Complaint.

21. Aventis denies the allegations set forth in paragraph 21 of the Complaint.

AFFIRMATIVE DEFENSES

1. Aventis incorporates by reference the responses and denials set forth in paragraphs 1 through 21.

2. Aventis has not infringed and does not infringe the '408 patent.

3. Aventis has not induced and does not induce infringement of the '408 patent.

4. Aventis has not contributed and does not contribute to the infringement of the '408 patent.

5. The claims of the '408 patent are invalid under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112.

6. The '408 patent is unenforceable due to Novo's inequitable conduct during prosecution of the application that issued as the '408 patent.

COUNTERCLAIMS

Aventis, for its counterclaims against Novo, alleges the following:

PARTIES

1. Aventis Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Sanofi-aventis S.A. is a corporation organized and existing under the laws of France, having a place of business at 174/180 Avenue de France, Paris, Cedex 75013 France. Sanofi-aventis Deutschland GmbH is a corporation organized and existing under the laws of Germany, having a place of business at Industriepark Hoechst, D – 65926 Frankfurt am Main, Germany.

2. Upon information and belief, Novo Nordisk A/S ("Novo") is a corporation organized and existing under the laws of Denmark, with offices located in Novo Allé, 2880 Bagsværd, Denmark.

JURISDICTION AND VENUE

3. Aventis's counterclaims against Novo arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, and under the Patent Laws of the United States, Title 35 United States Code. Accordingly, this Court has original and pendant subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

4. Venue in this judicial district is proper under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

FIRST COUNTERCLAIM COUNT: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '408 PATENT

5. Aventis incorporates by reference and realleges the allegations of counterclaim paragraphs 1 through 4, the defenses of affirmative defense paragraphs 1 through 6, and the responses and denials set forth in paragraphs 1 through 21.

6. Novo alleges in its Complaint that it owns the '408 patent and that Aventis infringes the '408 patent.

7. The pending litigation and disputes between Aventis and Novo establish an existing and actual case or controversy between them regarding whether Aventis infringes the '408 patent.

8. The manufacture, assembly, use, offer to sell, sale, distribution, or importation into the United States of the Aventis OptiClik™ device does not infringe and has not infringed the '408 patent, either literally or under the doctrine of equivalents.

9. Aventis does not infringe and has not infringed the '408 patent, either literally or under the doctrine of equivalents.

10. Aventis does not induce and has not induced infringement of the '408 patent.

11. Aventis does not contribute and has not contributed to the infringement of the '408 patent.

SECOND COUNTERCLAIM COUNT: DECLARATORY JUDGEMENT OF INVALIDITY OF THE '408 PATENT

12. Aventis incorporates by reference and realleges the allegations of counterclaim paragraphs 1 through 11, the defenses of affirmative defense paragraphs 1 through 6, and the responses and denials set forth in paragraphs 1 through 21.

13. The pending litigation and disputes between Aventis and Novo establish an existing and actual case or controversy between them regarding whether the '408 patent is invalid.

14. The claims of the '408 patent are invalid under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including, but not limited to, 35 U.S.C. § 102, 103, and/or 112.

THIRD COUNTERCLAIM COUNT: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '408 PATENT

15. Aventis incorporates by reference and realleges the allegations of counterclaim paragraphs 1 through 14, the defenses of affirmative defense paragraphs 1 through 6, and the responses and denials set forth in paragraphs 1 through 21.

16. The pending litigation and disputes between Aventis and Novo establish an existing and actual case or controversy between them regarding whether the '408 patent is unenforceable.

Introduction

17. The '408 patent is unenforceable as a result of Novo committing inequitable conduct in the United States Patent and Trademark Office ("the Patent Office") during prosecution of the application that issued as the '408 patent. Specifically, Novo failed to provide the examiner with highly material references, of which Novo was undoubtedly aware as the references are either Novo patents or references cited during prosecution of a related Novo patent application. All of the references disclose snap couplings in pen-type injector devices. Novo knew or should have known that the references were highly material to the patentability of the pending claims of '408 patent, yet it still withheld these references from the examiner.

The '408 Patent

18. Since its filing, the '408 patent (the '408 patent and its file history are attached as Exhibit 2) has always included at least one claim requiring "coupling means," the structure of which is defined by the specification as including snap couplings, such as snap locks. *See* '408 patent, col. 3, lines 15-25, 30-37 (Ex. 2, p. SAN00761331).

19. Novo argued during prosecution of the application that issued as the '408 patent that rotation of the main parts of the injector, *i.e.*, the cartridge assembly and the dosing assembly, could cause axial movement of the cartridge assembly relative to the dosing assembly. This axial movement would then result in the displacement of the plunger means from the stopper of the cartridge, causing an inaccurate dose. Therefore, Novo argued, it was necessary to select couplings between the cartridge assembly and the dosing assembly, and between the cartridge assembly and the needle assembly, that would prevent this rotation and the resulting displacement. During the course of prosecution, all claims of

the '408 patent were amended to recite that one of these couplings must be a "snap-lock." Ex. 2, p. SAN00761708 – 11.

20.

REDACTED

21. Novo argued that the claims of the '408 patent were patentable (i.e., novel and non-obvious) over the prior art because the '408 patent claims included a "snap lock" that was not disclosed by the prior art. Ex. 2, p. SAN00761706.

22. On January 27, 2003, in the prosecution of the '408 patent, the Patent Office issued a Notice of Allowance stating that the claims of the '408 patent were "allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means ***which comprises a snap lock***." Ex. 2, p. SAN00761714 (emphasis added).

The '011 Patent

23. While Novo was prosecuting the application that eventually matured into the '408 patent, it was also prosecuting the application that eventually matured into U.S. Patent No. 6,562,011 B1 ("the '011 patent"). The '011 patent and its file history are attached as Exhibit 6. The entire prosecutions of the '408 and '011 patents ran in parallel. Each of the '408 and '011 patents claim priority to two Danish patent applications and one U.S.

provisional application. Each priority document for the '408 patent was filed on the same date as a priority document for the '011 patent:

- On July 8, 1998, Novo filed PA 1998 00910 (Denmark) (Exhibit 3) to which the '408 patent claims priority and PA 1998 00909 (Denmark) (Exhibit 7) to which the '011 patent claims priority.
- On September 1, 1998, Novo filed U.S. Provisional Application 60/098,707 (Exhibit 4) to which the '408 patent claims priority and U.S. Provisional Application 60/098,702 (Exhibit 8) to which the '011 patent claims priority.
- On November 17, 1998, Novo filed PA 1998 01501 (Denmark) (Exhibit 5) to which the '408 patent claims priority and PA 1998 01500 (Denmark) (Exhibit 9) to which the '011 patent claims priority.

24. On July 7, 1999 and on July 8, 1999, Novo filed the nonprovisional applications for the '011 and the '408 patents, respectively. The nonprovisional applications were co-pending in the Patent Office for almost four years until the '011 and the '408 patents issued within two months of each other, on May 13, 2003 and June 24, 2003, respectively.

25. The priority documents PA 1998 00910 (Ex. 3) and PA 1998 00909 (Ex. 7) have substantially identical disclosures:

- The three figures in PA 1998 00910 are identical to the three figures in PA 1998 00909. Ex. 3, p. SAN00828636 – 37; Ex. 7, p. SAN00828385 – 86.
- The specification of PA 1998 00910 is substantially similar to that in PA 1998 00909; notably, the "Detailed [D]escription of the Invention" sections are nearly identical. Ex. 3, p. SAN00828629 – 32; Ex. 7, p. SAN00828378 – 81.

- The scope of the claims of PA 1998 00910 significantly coextends with the scope of the claims of PA 1998 00909. In particular, each priority document has medical delivery device claims describing cartridge assemblies, dosing assemblies, needle assemblies, unitarily molded cartridge devices, cartridge devices as housings, pierceable seals, stoppers, and the coupling means to interconnect the foregoing. Ex. 3, p. SAN00828633 – 35; Ex. 7, p. SAN00828382 – 84.

26. The priority documents PA 1998 01500 (Ex. 9) and PA 1998 01501 (Ex. 5) have substantially identical disclosures:

- The three figures in PA 1998 01500 are identical to the three figures in PA 1998 01501. Ex. 9, p. SAN00828400 – 01; Ex. 5, p. SAN00828651 – 52.
- The specification of PA 1998 01500 is substantially similar to that in PA 1998 01501; notably, the "Detailed [D]escription of the Invention" sections are nearly identical. Ex. 9, p. SAN00828393 – 96; Ex. 5, p. SAN00828644 – 47.
- The scope of the claims of PA 1998 01500 significantly coextends with the scope of the claims of PA 1998 01501. In particular, each priority document has medical delivery device claims describing cartridge assemblies, dosing assemblies, needle assemblies, unitarily molded cartridge devices, cartridge devices as housings, pierceable seals, stoppers, and the coupling means to interconnect the foregoing. Ex. 9, p. SAN00828397 – 99; Ex. 5, p. SAN00828648 – 50.

27. The '408 patent claims priority to Provisional Application 60/098,707 (Exhibit 4). The specification, claims, and figures of Provisional Application 60/098,707 are

substantially identical to those of PA 1998 00910 (Ex. 3). The '011 patent claims priority to Provisional Application 60/098,702 (Exhibit 8). The specification, claims, and figures of Provisional Application 60/098,702 are substantially identical to those of PA 1998 00909 (Ex. 7).

28. The '408 patent issued from Nonprovisional Application 09/349,748 ("the '748 application"), and the '011 patent issued from Nonprovisional Application 09/348,536 (the '536 application"). Both nonprovisional applications are substantially similar:

- The three figures in the '748 application are identical to the three figures in the '536 application. Ex. 2, p. SAN00761354 – 55; Ex. 6, p. SAN00828239 – 40.
- The specification of the '748 application is substantially similar to that in the '536 application; notably, the "Detailed [D]escription of the Invention" sections are nearly identical. Ex. 2, p. SAN00761342 – 45; Ex. 6, p. SAN00828230 – 32.
- As one example, the respective specifications both read:

  > In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

  Ex. 2, p. SAN00761339, lines 11 – 15; Ex. 6, p. SAN00828227, lines 6 – 9.

- As another example, the respective specifications both include a substantially identical description of coupling means, including a snap lock:

  > Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

  Ex. 2, p. SAN00761340, lines 16 – 19; Ex. 6, p. SAN00828228, lines 28 – 31.

29.

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30. The named inventors on the '408 and the '011 patents are identical. Ex. 2, p. SAN00761327; Ex. 6, p. SAN00828217.

31. The Combined Declaration for Patent Application and Power of Attorney forms for the '408 patent and the '011 patent list identical attorneys. Ex. 2, p. SAN00761352; Ex. 6, p. SAN00828252.

32. Both the '408 patent and the '011 patent discuss the problem of disengagement between the plunger means and the stopper means between uses of a delivery pen, as well as the very same solution to that problem. The '408 patent reads:

> [I]t is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly . . . [E]xamples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks.

'408 patent, col. 2, lines 54-58; col. 3, lines 23-25 (Ex. 2, p. SAN00761330 – 31).

Correspondingly, the '011 patent reads:

> Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly . . . [E]xamples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks.

'011 patent, col. 2, lines 44-50, 59-61 (Ex. 6, p. SAN00828220).

33. Both the '408 patent and the '011 patent discuss a particular method of molding the cartridge assembly. The '408 patent reads:

> In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge.

'408 patent, col. 3, lines 49-52. (Ex. 2, p. SAN00761331). The '011 patent similarly reads:

> In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

'011 patent, col. 3, lines 23-24. (Ex. 6, p. SAN00828221).

The Withheld References

34. During the prosecution of the '408 patent, Novo withheld eight material references from the examiner: United States Patent Nos. 6,004,297 ("the '297 patent"), 5,968,021 ("the '021 patent"), 5,331,954 ("the '954 patent"), 6,146,361 ("the '361 patent), 4,936,833 ("the '833 patent"), 5,549,575 ("the '575 patent"), 5,554,125 ("the '125 patent"), and 5,137,511 ("the '511 patent"). Each of these references disclosed a pen-type injector that included a snap coupling preventing the very type of rotation Novo argued to the Patent Office was a problem solved by the '408 patent. These withheld references are discussed in turn below.

A. The '297 Patent

35. The application that issued as the '297 patent was filed January 28, 1999 claiming priority to a provisional application filed February 5, 1998. Accordingly, the '297 patent is prior art to the '408 patent under at least 35 U.S.C. § 102(e). The '297 patent and its file wrapper are attached as Exhibit 10. The applications for the '297 patent and the '408 patent were co-pending in the Patent Office for a short time, and the '297 patent issued some

3 1/2 years before the '408 patent was issued, more than enough time to bring it to the attention of the patent examiner. The '297 patent is assigned to Novo Nordisk A/S.

36. The '297 patent is entitled "Injection Syringe" and discloses a pen-type injector of the same sort disclosed and claimed by the '408 patent. Additionally, the injector of the '297 patent includes a snap-lock coupling between the housing and the cartridge assembly:

> The syringe comprise [*sic*] a tubular housing **1** which is by a partition **15** divided into a first and a second division into the first one of which an ampoule holder **2** is snapped by a snap-lock comprising a ring shaped bead **3** on the ampoule holder **2** which bead is snapped into a corresponding circumferantial [*sic*] groove in the inner wall of the housing **1** near an open end thereof. By this snap connection the ampoule holder **2** is secured in the housing **1** so that it can be rotated but not axially displaced relative to this housing.

'297 patent, col. 5, lines 35-43 (Ex. 10).

37. Accordingly, the '297 patent discloses the very snap-lock coupling arrangement designed to prevent axial movement of the cartridge (ampoule) relative to the dosing assembly that is disclosed and claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

38. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '297 patent discloses such a snap coupling, and it would have supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '297 patent refutes Novo's argument that the '408 patent application presents a novel invention.

39. The '297 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '297 patent is a highly material reference with respect to the '408 patent.

B. The '021 Patent

40. The application that issued as the '021 patent was filed as a PCT application on February 27, 1995 and the application was given a 35 U.S.C. § 102(e) date of August 22, 1996. The '021 patent issued on October 19, 1999, some 9 months before the application for the '408 patent was filed. Accordingly, the '021 patent is prior art to the '408 patent under at least 35 U.S.C. § 102(e). The '021 patent and its file wrapper are attached as Exhibit 11. The '021 patent is assigned to Novo Nordisk A/S.

41. The '021 patent is entitled "Magazine and Removable Needle Unit" and discloses a needle unit having a sleeve "designed to be snap-locked onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging a circumferential recess in the outer wall of the connecting piece." '021 patent, Abstract (Ex. 11). The summary of the invention states that "[t]he object of the invention is to provide a needle unit of the snap-on type, which may easily be snapped onto a durable pen type syringe and which may easily be dismounted from the syringe to make it possible to change the needle without having to dispose of the syringe." '021 patent, col. 1, lines 46-50 (Ex. 11).

42. Thus, the '021 patent describes a snap-lock coupling for attaching a needle to the cartridge assembly of a pen-type injector device, exactly a claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of

Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

43. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '021 patent discloses such a snap coupling, and it would have supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '021 patent refutes Novo's argument that the '408 patent application presents a novel invention.

44. The '021 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '021 patent is a highly material reference with respect to the '408 patent.

C. The '954 Patent

45. The '954 patent issued July 26, 1994, some 5 years before the application for the '408 patent was filed, and accordingly it is prior art to the '408 patent under at least 35 U.S.C. § 102(e). The '954 patent and its file wrapper are attached as Exhibit 12. The '954 patent is assigned to Novo Nordisk A/S.

46. The '954 patent is entitled "Device for Nasal Delivery of Liquid Medications" and discloses a pen-shaped device for nasal administration of a liquid medicine. Essentially, it is pen-type injector without a needle. The device of the '954 patent includes first and second housing elements "coupled together to allow rotation but no axial displacement of the first housing element with respect to the second housing element." '954 patent, col. 1, lines 54-56 (Ex. 12). The first housing element carries a cartridge of medication, analogous to the

cartridge assembly of the '408 patent, while the second housing element contains dosing and delivery mechanics, analogous to the dosing assembly of the '408 patent. '954 patent, col. 1, line 56 – col. 2, line 13 (Ex. 12). The coupling between the housing elements is further described as follows:

> **FIG. 1** shows a pen shaped device having a first housing element **1** and a second housing element **2** snapped together by an external bead **3**, and the first housing element **1** being snapped into an annular groove **4** in the second housing element **2** permitting the two housing elements to be rotated in relation to each other about the common length axis, but not to be displaced in relation to each along this axis.

'954 patent, col. 4, lines 3-10 (Ex. 12).

47. Thus, the '954 patent discloses exactly the snap-lock coupling between the cartridge assembly and the dosing assembly as that disclosed and claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

48. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '954 patent discloses such a snap coupling, and it would have supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '954 patent refutes Novo's argument that the '408 patent application presents a novel invention.

49. The '954 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '954 patent is a highly material reference with respect to the '408 patent.

D. The '361 Patent

50. In an Office Action dated January 17, 2001, for the application that became the '011 patent, the examiner cited the '361 patent to Novo. Ex. 6, p. SAN00828295 – 302.

51. The '361 patent was filed on September 26, 1996 making it prior art to the '408 patent under at least 35 U.S.C. § 102(e). The '361 patent is attached as Exhibit 13. The '361 patent was never mentioned or referenced by either the examiner or Novo during the prosecution of the '408 patent. The prosecution of the '408 patent continued for more than two years after the '361 patent came to the attention of Novo.

52. The '361 patent discloses a needle assembly that could be snap-fit on to a cartridge retainer assembly:

> Cap **56** of needle assembly **46** includes an array of internal threads (not shown) for removable mounting needle assembly **46** to needle mounting insert tip **20** on cartridge retainer assembly **10**. It is to be understood, however, that other releasable engagement means between needle assembly **46** and cartridge retainer assembly can be provided. For example, external threads can be formed on needle assembly **46** and corresponding internal threads can be defined on cartridge retainer assembly **10** or a bayonet style mounting using lugs and slots can be used. In addition, **needle assembly 46 could be "snap-fit" on to cartridge retainer assembly 10.**

'361 patent, col. 3, lines 50-62 (emphasis added) (Ex. 13).

53. Thus, the '361 patent discloses a means for coupling a needle assembly to a cartridge assembly that included a snap coupling – e.g., a snap-fit – as claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

54. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '361 patent discloses such a snap coupling, and it would have supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '361 patent refutes Novo's argument that the '408 patent application presents a novel invention.

55. The '361 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '361 patent is a highly material reference with respect to the '408 patent.

E. The '833 Patent

56. In the prosecution of the '011 patent, in an Information Disclosure Statement dated January 26, 2000, Novo cited the '833 patent as being material to the prosecution of the '011 patent. Ex. 6, p. SAN00828277 – 79. The '833 patent was filed on August 23, 1998 making it prior art to the '408 patent at least under 35 U.S.C. § 102(e). The '833 patent is attached as Exhibit 14.

57. Novo filed a Supplemental Information Disclosure Statement for the application that became the '408 patent on February 2, 2000 (Ex. 2, p. SAN00761569 – 73); however, the '833 patent was not mentioned then, nor ever, during the prosecution of the '408 patent. The prosecution of the '408 patent continued for more than three years after the '833 patent was cited by Novo during the prosecution of the '011 patent.

58. The '833 patent is entitled "Cartridge-Holder Assembly for Medication Dispensing Unit" and discloses a syringe-type medication dispensing unit that includes a

cartridge, a cartridge holder, and a dosing assembly (referred to as a "dispensing device"). '833 patent, Abstract; col. 5, line 42-43 (Ex. 14). The dispensing device is designed so as "prevent rearward movement of the plunger **5** once the [cartridge] housing **120** is in place." '833 patent, col. 6, lines 51-52 (Ex. 14).

59. The teaching of the '833 patent includes snap couplings:

> The above device can be manufactured in many suitable materials and **readily lends itself** to manufacture by injection molding of suitable plastics materials with the **various components being snap fits** upon one another.

'833 patent, col. 9, lines 38-41 (emphasis added) (Ex. 14). Thus, the '833 patent discloses a means for coupling a needle assembly to a cartridge assembly that included a snap coupling – e.g., a snap-fit – as claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

60. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '833 patent discloses such a snap coupling, and it would have supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '833 patent refutes Novo's argument that the '408 patent application presents a novel invention.

61. The '833 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '833 patent is a highly material reference with respect to the '408 patent.

F. The '575 Patent

62. In an Information Disclosure Statement dated January 26, 2000, Novo cited the '575 patent as possibly being material to the prosecution of the '011 patent. Ex. 6, p. SAN00828277 – 79. The '575 patent was filed on September 13, 1994 making it prior art to the '408 patent at least under 35 U.S.C. § 102(e). The '575 patent is attached as Exhibit 15. The '575 patent discloses a cartridge retainer assembly for a medication delivery pen with a snap fit needle assembly. '575 patent, col. 3, line 65 – col. 4, line 4 (Ex. 15).

63. On February 2, 2000, a week after Novo cited the '575 patent in the '011 prosecution, Novo filed a Supplemental Information Disclosure Statement for the application that became the '408 patent (Ex. 2, p. SAN00761569 – 73); however, Novo failed to disclose the '575 patent then, or ever, during the prosecution of the '408 patent. The prosecution of the '408 patent continued for more than three years after the '575 patent was cited by Novo.

64. The '575 patent discloses a needle assembly snap-fit on to a cartridge retainer assembly as claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

65. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '575 patent discloses such a snap coupling, and it would have supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '575 patent refutes Novo's argument that the '408 patent application presents a novel invention.

66. The '575 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '575 patent is a highly material reference with respect to the '408 patent.

G. The '125 Patent

67. Additionally, two references disclosing snap features were cited by the examiner in an April 26, 2000 Office Action during the prosecution of the '011 patent. Ex. 6, p. SAN00828269 – 76. One of these references was the '125 patent.

68. The '125 patent was filed on May 17, 1994 making it prior art at least under 35 U.S.C. §102(e). The '125 patent is attached as Exhibit 16. The '125 patent discloses a prefilled vial syringe with various snap lock connections. '125 patent, col. 10, lines 26-30; col. 13, lines 38-40; col. 15, lines 14-19; col. 15, lines 30-32; claim 16, col. 16, lines 47-49 (Ex. 16).

69. The application that became the '408 patent was pending for at least two and a half years in the Patent Office after the '125 patent came to Novo's attention.

70. The '125 patent discloses a syringe with snap couplings as claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

71. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '125 patent discloses such a snap coupling, and it would have

supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '125 patent refutes Novo's argument that the '408 patent application presents a novel invention.

72. The '125 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '125 patent is a highly material reference with respect to the '408 patent.

H. The '511 Patent

73. Also in the April 26, 2000 Office Action during the prosecution of the '011 patent, the examiner cited the '511 patent to Novo. Ex. 6, p. SAN00828269 – 76.

74. The '511 patent was filed on November 16, 1989 making it prior art to the '408 patent at least under 35 U.S.C. § 102(e). The '511 patent is attached as Exhibit 17. The '511 patent is in the same family as the '125 patent, and it contains similar disclosures regarding a syringe with snap fit couplings. '511 patent, col. 11, lines 28-30; claim 9, col. 16, lines 32-33 (Ex. 17).

75. The application that became the '408 patent was pending for at least two and a half years in the Patent Office after the '511 patent came to Novo's attention.

76. The '511 patent discloses a syringe with snap couplings as claimed by the '408 patent. It cannot be said to be cumulative of other art before the examiner. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose such a snap coupling. Ex. 2, p. SAN00761714.

77. As argued by Novo, the only reason that the '408 patent claims were allowed over the prior art before the examiner was because the claims required a snap coupling. Ex. 2, p. SAN00761706. The '511 patent discloses such a snap coupling, and it would have supported at least a prima facie case of unpatentability had it been before the examiner during the prosecution of the '408 patent. Furthermore, the very existence of the '511 patent refutes Novo's argument that the '408 patent application presents a novel invention.

78. The '511 patent is not cumulative, its teachings constitute a prima facie case of the unpatentability of the '408 patent, and it is inconsistent with arguments advanced by Novo during the prosecution of the '408 patent. Therefore, the '511 patent is a highly material reference with respect to the '408 patent.

Attorneys Involved in the Prosecution of the '408 Patent

A. Steve Zelson

79. **REDACTED**

80. From the filing of the '408 patent on July 8, 1999 until at least August 2001, all correspondence from the Patent Office regarding the prosecution of the '408 patent application was directed to Mr. Zelson. **REDACTED**

81. Mr. Zelson was the primary prosecuting attorney for the '954 patent. *See* Ex. 12.

82. All correspondence from the Patent Office for the applications that became the '297, the '021, and the '954 patents was directed to Steve Zelson from filing until issuance. *See* Ex. 10, Ex. 11, Ex. 12.

83. The '297, the '021, and the '954 patents all list Mr. Zelson as "Attorney, Agent, or Firm" on their faces. Ex. 10, Ex. 11, Ex. 12.

84. Since Mr. Zelson was responsible for the prosecution of the '297, the '021, and the '954 patents, as well as the '408 patent, he knew or should have known of the materiality of the '297, the '021, and the '954 patents to the '408 patent. Despite the individual materiality of each of those Novo patents, not to mention the materiality of all three taken together, Mr. Zelson disclosed none of them to the Patent Office in connection with the prosecution of the '408 patent. Given the high materiality of these Novo patents, one must conclude that Mr. Zelson withheld these patents with the intent to deceive the Patent Office.

85. From the filing of the '011 patent on July 7, 1999 until at least August 2001, all correspondence from the Patent Office regarding the prosecution of the '011 patent application was directed to Mr. Zelson. **REDACTED**

86. During the prosecution of the '011 patent, the examiner cited the '125 and the '511 patents in an Office Action that was sent to Mr. Zelson on April 26, 2000. Ex. 6, p. SAN00828269 – 76.

87. During the prosecution of the '011 patent, the examiner cited the '361 patent in an Office Action that was sent to Mr. Zelson on January 17, 2001. Ex. 6, p. SAN00828295 – 302.

88. Becuase Mr. Zelson was responsible for the prosecution of both the '011 and the '408 patents, he knew of the '361, the '511 and the '125 patents cited during prosecution of the '011 patent, and he knew or should have known of their materiality to the '408 patent. Despite the individual materiality of each of those references, not to mention the materiality

of all three taken together, Mr. Zelson disclosed none of them to the Patent Office in connection with the prosecution of the '408 patent. Given the high materiality of these references, one must conclude that Mr. Zelson withheld these references with the intent to deceive the Patent Office.

B. Elias Lambiris

89. Mr. Lambiris filed the nonprovisional application for the '408 patent. Ex. 2, p. SAN00761364.

90. Twice, on September 17, 1996 and on August 6, 1996, Mr. Lambiris submitted formal drawing sheets for the '021 patent. Ex. 11. Also, on August 22, 1996, Mr. Lambiris filed both a preliminary amendment and an Information Disclosure Statement for the '021 patent. Ex. 11.

91. On January 28, 1999, Mr. Lambiris filed the nonprovisional application for the '297 patent. Ex. 10.

92. On November 12, 1999, Mr. Lambiris filed an Information Disclosure Statement including twelve references for the application that became the '408 patent. Ex. 2, p. SAN00761370 – 72.

93. On January 26, 2000, Carol Rozek filed an Information Disclosure Statement for the '011 patent application that included ten references total, six of which appeared in Mr. Lambiris's November 12, 1999 Information Disclosure Statement. Ex. 6, p. SAN00828277 – 79.

94. A week after Ms. Rozek's January 26, 2000 Information Disclosure Statement, on February 2, 2000, Mr. Lambiris filed a Supplemental Information Disclosure Statement for the '408 patent application. Ex. 2, p. SAN00761569 – 73. The only reference

in this Supplemental Statement was U.S. Patent No. 5,688,251 (the '251 patent). The '251 patent is one of the four new references that Ms. Rozek had cited on January 26, 2000. Ex. 6, p. SAN00828277. The other three new references from Ms. Rozek's Information Disclosure Statement, including the '833 and the '575 patents, were not cited by Mr. Lambiris during the prosecution of the '408 patent.

95. Mr. Lambiris was responsible for the prosecution of the '408 patent, he knew of the '021 and the '297 patents, he knew of the '833, and the '575 patents cited during prosecution of the '011 patent, and he knew or should have known of the materiality of all of these references to the '408 patent. Despite the individual materiality of each of those references, Mr. Lambiris failed to disclose any of them to the Patent Office in connection with the prosecution of the '408 patent. Given the high materiality of these references, one must conclude that Mr. Lambiris withheld these references with the intent to deceive the Patent Office.

C. Robert Smith

96. Robert Smith, a patent attorney with the law firm of Skadden, Arps, Slate, Meagher & Flom, substantively prosecuted the '408 patent application, and this included writing and filing multiple Office Action responses between June 2001 and February 2002. Ex. 2.

97. Mr. Smith, then with the law firm of White & Case, substantively prosecuted the '021 patent application, and this included writing and filing multiple Office Action responses between April 1998 and April 1999. Ex. 11.

98. Mr. Smith, while still with White & Case, filed an Amended Abstract for the '297 patent in July 1999. Ex. 10.

99. Mr. Smith was responsible for the prosecution of the '408 patent, he knew of the '021 and the '297 patents, and he knew or should have known of their materiality to the '408 patent. Despite the individual materiality of each of those references, Mr. Smith failed to disclose either of them to the Patent Office in connection with the prosecution of the '408 patent. Given the high materiality of these references, one must conclude that Mr. Smith withheld these references with the intent to deceive the Patent Office.

100. Mr. Smith, while with Skadden, Arps, Slate, Meagher & Flom, substantively prosecuted the '011 patent application, and this included writing multiple Office Action responses between June 2001 and February 2002. Ex. 6.

101. During the prosecution of the '011 and '408 patents, Mr. Smith had intimate knowledge of the '361 patent for at least the reason that in the prosecution of the '011 patent, Mr. Smith specifically and substantively argued the '361 patent in his Response After Final Rejection dated June 11, 2001. Ex. 6, p. SAN00828305 – 09. Later in the prosecution of the '011 patent application, Mr. Smith again substantively argued the '361 patent in his Response to Office Action dated October 25, 2001. Ex. 6, p. SAN00828324 – 29.

102. Mr. Smith urged the examiner to interpret the '361 patent in conjunction with a similar reference, the '251 patent, a reference that Novo disclosed during the prosecution of the '408 patent. Specifically, Mr. Smith noted that "[t]he commonly owned Chanoch [the '251] and DiBiasi [the '361] patents both show a syringe having a cartridge holder element . . .[and] [t]he cartridge holder and cartridge holder in [the '361 patent] are very similar to the cartridge holder and cartridge shown in [the '251 patent]." Ex. 6, p. SAN00828327 – 28.

103. Novo considered the '251 patent material enough to the patentability of the '408 patent that it was the only reference in a Supplementary Information Disclosure Statement submitted to the Patent Office on February 2, 2000. Ex. 2, p. SAN00761569 – 73.

104. Because Mr. Smith had intimate knowledge of the '361 patent and considered it "very similar" to another reference that was disclosed during the prosecution of the '408 patent application, he knew or should have known of the materiality of the '361 patent to the prosecution of the '408 patent. Despite its prominent role in the prosecution of the related '011 patent, the '361 patent was never disclosed, by Mr. Smith or by anyone else involved, in connection with the '408 patent.

105. In light of the high materiality of the '361 patent, one must conclude that Mr. Smith withheld the '361 patent during the prosecution of the '408 patent with the intent to deceive the Patent Office.

D. Marc Began

106. Marc Began of Novo prosecuted both the '408 and the '011 patents between July 2002 and their respective issuances in May and June 2003. Ex. 2, Ex. 6. Mr. Began also filed a Request for a Certificate of Correction in August 2005 for the '408 patent. Ex. 2, p. SAN00761721 – 23.

107. Mr. Began is listed on the face of both the '011 patent and the '408 patent as "Attorney, Agent, or Firm." Ex. 6, p. SAN00828217; Ex. 2, p. SAN00761327.

108. Since Mr. Began was responsible for the prosecution of both the '011 and the '408 patents, he knew of the '361, the '833, the '575, the '511 and the '125 patents cited during prosecution of the '011 patent, and he knew or should have known of their materiality to the '408 patent. Despite the individual materiality of each of those references, not to

mention the materiality of all five taken together, Mr. Began disclosed none of them to the Patent Office in connection with the prosecution of the '408 patent. Given the high materiality of these references, one must conclude that Mr. Began withheld these references with the intent to deceive the Patent Office.

Conclusion

109. During the prosecution of the '408 patent, Novo failed to disclose three of its own patents that disclose snap couplings, despite the fact that some of the same attorneys who prosecuted those patents also prosecuted the '408 patent. Additionally, during the prosecution of the '011 patent – a patent closely related to the '408 patent – five references emerged that also disclosed snap couplings. Novo and its attorneys undeniably knew of these references during prosecution of the application that issued as the '408 patent, yet they continued to withhold the references from the examiner. Particularly in view of the examiner's Statement of Reasons for Allowance stressing both the importance of the snap coupling to the patentability of the '408 patent and the dearth of prior art on such couplings, these references would each have been noncumulative. Additionally, each reference would have both supported a prima facie case of the unpatentability of the '408 patent and belied Novo's assertions that the '408 patent was novel and nonobivous. Given the high degree of materiality of each reference, not to mention the materiality of all eight references taken together, there can be no question that the references were withheld deliberately and with an intent to deceive the Patent Office. It is beyond the bounds of credibility to argue that Novo innocently failed to cite these references considering Novo's intimate connection with each withheld reference. Accordingly, one must conclude that Novo's withholding of the

references was deliberate and with the requisite intent to justify a finding of inequitable conduct and a declaration that the '408 patent is unenforceable.

RELIEF REQUESTED

WHEREFORE, Defendant respectively requests that this Court:

(A) Dismiss with prejudice the Complaint of Novo and deny all of Novo's requests for relief;

(B) Declare the '408 patent not infringed;

(C) Declare the '408 patent invalid;

(D) Declare the '408 patent unenforceable;

(E) Enter a permanent injunction enjoining Novo from asserting or otherwise seeking to enforce the '408 patent against sanofi-aventis S.A., Aventis Pharmaceuticals Inc., sanofi-aventis Deutschland GmbH, or any of their customers;

(F) Declare this case exceptional under 35 U.S.C. § 285;

(G) Award Aventis its costs, disbursements, and reasonable attorney fees (including expert fees) incurred in this action; and

(H) Enter such other and further relief as the Court deems just and proper.

ASHBY & GEDDES

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